

[Counsel listed on signature pages]

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

**In re LIDODERM ANTITRUST  
LITIGATION**

Case No. 14-md-02521-WHO

THIS DOCUMENT RELATES TO:  
ALL DIRECT PURCHASER ACTIONS

**DIRECT PURCHASER  
PLAINTIFFS' CONSOLIDATED  
AMENDED CLASS ACTION  
COMPLAINT**

DEMAND FOR JURY TRIAL

1 Plaintiffs Droguería Betances, Inc. (“Betances”), Rochester Drug Co-Operative,  
2 Inc. (“RDC”), American Sales Company, LLC (“ASC”), and Cesar Castillo, Inc.  
3 (“Castillo”) (collectively, “Plaintiffs”), bring this class action on behalf of themselves  
4 and all others similarly situated against defendants Endo Pharmaceuticals Inc.  
5 (“Endo”), Teikoku Pharma USA (“Teikoku Pharma”), Teikoku Seiyaku Co.  
6 (“Teikoku Seiyaku”) (collectively “Teikoku”) (together, “Endo/Teikoku”), Watson  
7 Pharmaceuticals, Inc., and Actavis, plc, formerly known as Watson Pharmaceuticals,  
8 Inc., and Watson Laboratories, Inc. (collectively, “Watson”) (together with  
9 Endo/Teikoku, the “Defendants”) and allege as follows based on: (a) personal  
10 knowledge; (b) the investigation of their counsel; and (c) information and belief.

## 11 I. NATURE OF THE ACTION

12 1. This is a civil antitrust action brought by Plaintiffs on behalf of a class of  
13 direct purchasers of lidocaine patch 5%, sold by Endo under the brand name  
14 Lidoderm. Lidoderm is a lidocaine-containing patch for the treatment of pain  
15 associated with post-herpetic neuralgia. Plaintiffs seek overcharge damages arising  
16 out of Endo/Teikoku’s unlawful agreement with Watson not to compete in the market  
17 for lidocaine patch 5%.

18 2. On May 28, 2012, Endo/Teikoku entered into an unlawful non-competition  
19 agreement with Watson. Under the agreement (the “Reverse Payment Agreement” or  
20 “Agreement”), Watson agreed to delay marketing its less-expensive generic version of  
21 Lidoderm for almost 13 months, until September 15, 2013. In exchange,  
22 Endo/Teikoku agreed to pay Watson — and did, in fact, pay Watson — (a) at least  
23 \$96 million in the form of branded Lidoderm at no cost to Watson, which Watson  
24 could then resell (and did, in fact, resell) at that price; and (b) by forbearing from  
25 launching an authorized generic to compete with Watson’s generic Lidoderm until 7½  
26 months after Watson’s generic belatedly entered the market, effectuating a payment of  
27

1 hundreds of millions of dollars from Endo/Teikoku to Watson. In compliance with the  
2 Agreement, even though Watson was granted final FDA approval to launch its less-  
3 expensive generic Lidoderm patch on August 23, 2012, Watson did not come to  
4 market until September 15, 2013, thirteen (13) months later.

5 3. But for Defendants' unlawful Reverse Payment Agreement, one or more  
6 generic versions of Lidoderm would have entered the market as early as August 23,  
7 2012. Thus, absent Defendants' unlawful Reverse Payment Agreement, Plaintiffs and  
8 the members of the class would have been able to satisfy their lidocaine patch 5%  
9 requirements at significantly lower prices substantially earlier than they did, rather  
10 than being forced to pay for brand and generic Lidoderm at higher prices because of  
11 the unlawful agreement. Endo stated in its annual report that revenue from sales of  
12 Lidoderm was \$825 million in 2011 and \$947 million in 2012.

13 4. Defendants' unlawful Reverse Payment Agreement was designed to and did  
14 in fact: (i) delay and/or preclude the entry of less-expensive generic versions of  
15 lidocaine patch 5%; (ii) delay the introduction of an authorized generic lidocaine patch  
16 5%, which otherwise would have appeared on the market at a significantly earlier time  
17 and lowered prices further; (iii) fix, raise, maintain or stabilize the prices of lidocaine  
18 patch 5% products; (iv) permit Endo/Teikoku to maintain a monopoly for lidocaine  
19 patch 5%; (v) allocate 100% of the lidocaine patch 5% market in the United States,  
20 including its territories, possessions and the Commonwealth of Puerto Rico, to  
21 Endo/Teikoku for up to 13 months; and (vi) allocate 100% of generic lidocaine patch  
22 5% sales in the United States, including its territories, possessions and the  
23 Commonwealth of Puerto Rico, to Watson for 7½ months.

24 5. Defendants thus violated §§ 1 and 2 of the Sherman Act through their  
25 anticompetitive Reverse Payment Agreement, which unreasonably restrained  
26 competition in the market for lidocaine patch 5% and improperly maintained and  
27

1 extended Endo/Teikoku's market and monopoly power by foreclosing or delaying  
2 competition from lower-priced generic versions of lidocaine patch 5%.

## 3 **II. JURISDICTION AND VENUE**

4 6. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1  
5 and 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover  
6 threefold damages, costs of suit and reasonable attorneys' fees for the injuries  
7 sustained by Plaintiffs and members of the class (defined below) resulting from  
8 Defendants' unlawful restraint of trade and maintenance of market and monopoly  
9 power in the market for lidocaine patch 5% in the United States, including its  
10 territories, possessions and the Commonwealth of Puerto Rico. The Court has subject  
11 matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

12 7. Defendants transact business within this district, and they carry out interstate  
13 trade and commerce in substantial part in this district and/or have an agent and/or can  
14 be found in this district. Defendant Teikoku has a principal place of business in this  
15 district. Venue is therefore appropriate within this district under section 12 of the  
16 Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

## 17 **III. INTRADISTRICT ASSIGNMENT**

18 8. Assignment to this division in this District is proper because the interstate  
19 trade and commerce involved and affected by the violations of the antitrust laws was  
20 and is carried out within this division, and this action has been transferred to this  
21 division by the Judicial Panel on Multi-District Litigation.

## 22 **IV. PARTIES**

### 23 **A. Plaintiffs**

24 9. Betances is a corporation organized under the laws of the Commonwealth of  
25 Puerto Rico and located at Ave. Luis Munoz Marin Esq. El Troche Final, Caguas,  
26 Puerto Rico 00725. During the Class period (defined below), Betances purchased  
27

1 branded Lidoderm directly from Endo/Teikoku, and purchased generic Lidoderm  
2 directly from Watson, and was injured as a result of Defendants' unlawful conduct.

3 10. RDC is a stock corporation duly formed and existing under the New York  
4 Cooperative Corporations Law, with its principal place of business located at 50 Jet  
5 View Drive, Rochester, New York 14624. During the Class period, RDC purchased  
6 branded Lidoderm directly from Endo/Teikoku, and purchased generic Lidoderm  
7 directly from Watson, and was injured as a result of Defendants' unlawful conduct.

8 11. ASC is a Delaware limited liability company with its principal place of  
9 business in Lancaster, Erie County, New York. ASC brings this action on its own  
10 behalf and as an assignee of McKesson Corporation. During the Class period, ASC  
11 purchased (a) branded Lidoderm directly from Anda Pharmaceuticals, Inc., a wholly-  
12 owned subsidiary of Watson; (b) branded Lidoderm from McKesson Corporation,  
13 which purchased directly from Endo/Teikoku; and (c) generic Lidoderm directly from  
14 Watson. ASC was injured as a result of Defendants' unlawful conduct.

15 12. Castillo is a corporation organized under the laws of the Commonwealth  
16 of Puerto Rico, with its principal place of business located at Bo. Quebradas Arena,  
17 Rd. #1 Km. 26.0, Río Piedras, Puerto Rico, 00926. During the Class period, Castillo  
18 purchased branded Lidoderm directly from Endo/Teikoku and was injured as a result  
19 of Defendants' unlawful conduct.

## 20 **B. Defendants**

21 13. Endo is a Delaware corporation, having its principal place of business at  
22 1400 Atwater Drive, Malvern, Pennsylvania, 19355. Endo markets and sells  
23 Lidoderm throughout the United States.

24 14. Teikoku Seiyaku is a company organized and existing under the laws of  
25 Japan, having its principal place of business in Higashikagawa, Kagawa, Japan.  
26 Teikoku Seiyaku is the owner, assignee or licensee of U.S. Patent No. 5,827,529 (the  
27

1 “529 patent”) over which Endo and Teikoku sued Watson. Teikoku Seiyaku  
2 manufactures Lidoderm in Japan for commercial sale in the United States by Endo  
3 under a Manufacturing and Supply Agreement with Endo. Endo pays Teikoku  
4 Seiyaku royalties under that agreement.

5 15. Teikoku Pharma is a California corporation, having its principal place of  
6 business at 1718 Ringwood Avenue, San Jose, California, 95131. Teikoku Pharma is  
7 a wholly-owned subsidiary of Teikoku Seiyaku, and is the holder of the New Drug  
8 Application for Lidoderm.

9 16. Actavis, plc is incorporated under the laws of Ireland, having its  
10 principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland.  
11 Actavis, plc also has a place of business at Morris Corporate Center III, 400 Interpace  
12 Parkway, Parsippany, New Jersey, 07054.

13 17. Defendant Watson Pharmaceuticals, Inc. was a Nevada corporation,  
14 having its principal place of business at 311 Bonnie Circle, Corona, California, 92880.  
15 As a result of Watson Pharmaceuticals, Inc.’s acquisition of Actavis Group in or  
16 around October 2012, effective on or about January 24, 2013, Watson  
17 Pharmaceuticals, Inc. changed its name to Actavis, Inc. Actavis, Inc. changed its  
18 name to Actavis, plc on or about October 1, 2013.

19 18. Defendant Watson Laboratories, Inc. is a Nevada corporation, having its  
20 principal place of business at Morris Corporate Center III, 400 Interpace Parkway,  
21 Parsippany, New Jersey 07054. Defendant Watson Laboratories, Inc. was a wholly-  
22 owned subsidiary of Watson Pharmaceuticals, Inc. and is now a subsidiary of Actavis,  
23 plc.

24 19. Watson was and is engaged in marketing, production and distribution of  
25 generic pharmaceutical products, including through its wholly-owned wholesaler  
26  
27

1 affiliates including Anda, Inc., Anda Pharmaceuticals, Inc., and Valmed  
2 Pharmaceuticals, Inc.

3 20. All of Defendants' actions described in this complaint are part of, and in  
4 furtherance of, the unlawful conduct alleged herein, and were authorized, ordered,  
5 and/or done by Defendants' various officers, agents, employees, or other  
6 representatives while actively engaged in the management of Defendants' affairs (or  
7 that of their predecessors-in-interest) within the course and scope of their duties and  
8 employment, and/or with the actual, apparent, and/or ostensible authority of  
9 Defendants.

10 21. With respect to all of the conduct complained of below, at all relevant  
11 times Endo acted in concert with Teikoku Pharma and Teikoku Seiyaku. Moreover,  
12 Endo, Teikoku Pharma, and Teikoku Seiyaku each signed the Reverse Payment  
13 Agreement with Watson. Furthermore, Endo, Teikoku Pharma, and Teikoku Seiyaku  
14 at all relevant times acted as a single entity with respect to the material provisions and  
15 performance of the Reverse Payment Agreement, which refers to Endo, Teikoku  
16 Pharma, and Teikoku Seiyaku collectively in provisions relating to the grant of patent  
17 licenses to Watson, the agreement not to launch a competing authorized generic for  
18 7½ months, and the obligation to deliver free brand Lidoderm product to pay Watson.  
19 On information and belief, Endo, Teikoku Pharma, and Teikoku Seiyaku are involved  
20 in a marketing enterprise that covers the distribution and marketing of Lidoderm in the  
21 United States.

## 22 V. CLASS ACTION ALLEGATIONS

23 22. Plaintiffs bring this action on behalf of themselves and, under Rule 23(a)  
24 and (b)(3) of the Federal Rules of Civil Procedure, as representatives of a Class  
25 defined as follows:

26 All persons or entities in the United States, including its territories,  
27 possessions, and the Commonwealth of Puerto Rico, who purchased brand

1 or generic Lidoderm directly from any of the Defendants at any time  
2 during the period August 23, 2012 through the date on which the  
3 anticompetitive effects of Defendants' challenged conduct cease (the  
4 "Class").

5 Excluded from the Class are Defendants and their officers, directors,  
6 management, employees, subsidiaries, and affiliates, and all federal  
7 governmental entities.

8 23. Joinder of the members of the Class is impracticable. Plaintiffs believe  
9 the Class members are numerous and widely dispersed throughout the United States  
10 and its territories, possessions and the Commonwealth of Puerto Rico. Further, the  
11 Class is readily identifiable from information and records in the possession of  
12 Defendants. Direct notice to the members of the Class can be made upon obtaining  
13 the relevant information and records in the possession of Defendants.

14 24. Plaintiffs' claims are typical of the claims of the members of the Class.  
15 Plaintiffs and all members of the Class were damaged by the same wrongful conduct  
16 by Defendants, *i.e.*, they paid artificially inflated prices for lidocaine patch 5% and  
17 were deprived of the benefits of competition from less-expensive generic versions of  
18 Lidoderm as a result of Defendants' wrongful conduct.

19 25. Plaintiffs will fairly and adequately protect and represent the interests of  
20 the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the  
21 Class.

22 26. Plaintiffs are represented by counsel who are experienced and competent  
23 in the prosecution of class action antitrust litigation, and have particular experience  
24 with class action antitrust litigation in the pharmaceutical industry.

25 27. Questions of law and fact common to the members of the Class  
26 predominate over questions, if any, that may affect only individual Class members,  
27 because Defendants have acted on grounds generally applicable to the entire Class.  
28 Such generally applicable conduct is inherent in Defendants' wrongful conduct.

28. Questions of law and fact common to the Class include:

- a. Whether the pay-for-delay conduct alleged herein constitutes a violation of the antitrust laws;
- b. whether Defendants conspired to suppress generic competition to Lidoderm;
- c. whether, pursuant to the Agreement, Watson agreed to, and did, delay its entry into the market with generic Lidoderm;
- d. whether, pursuant to the Agreement, Endo/Teikoku made payments to Watson, and the amounts of each payment;
- e. whether payments Endo/Teikoku made to Watson were for a purpose other than delaying Watson's entry into the market for lidocaine patch 5%;
- f. whether there are legitimate procompetitive justifications explaining Endo/Teikoku's payments to Watson, such as being merely for avoided litigation costs or for services Watson was to perform for Endo/Teikoku;
- g. whether Defendants' Agreement suppressed generic competition to Lidoderm;
- h. whether Defendants' Agreement harmed competition in the lidocaine patch 5% market;
- i. whether Defendants conspired or attempted to maintain Endo/Teikoku's market and/or monopoly power in the lidocaine patch 5% market;
- j. whether Endo/Teikoku possessed market and/or monopoly power in the market for lidocaine patch 5%;

- k. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- l. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- m. whether, and to what extent, Defendants' challenged conduct caused antitrust injury to the business or property of Plaintiffs and the members of the Class in the nature of overcharges; and
- n. the quantum of overcharges paid by the Class in the aggregate.

29. Class action treatment is a superior method for the fair and efficient adjudication of the controversy because, in addition to other benefits, such treatment will permit a large number of similarly situated persons to prosecute their claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining overcharge damages for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

30. Plaintiffs know of no difficulty to be encountered in the maintenance of this action as a class action that would preclude its maintenance as a class action.

## VI. REGULATORY BACKGROUND

### A. The Regulatory Structure for Approval of Generic Drugs

31. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer who creates a new drug must obtain the approval of FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

32. When FDA approves a brand manufacturer's NDA, the brand manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the "Orange Book") any patent that claims either the approved drug or approved methods of use of the drug and could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand drug prior to the expiration of the listed patent(s). Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

33. FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

## 1. The Hatch-Waxman Amendments

34. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug — that is, that the generic drug is both pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq.*

35. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active

1 ingredients, having the same route of administration and dosage form, and meeting  
2 applicable standards of strength, quality, purity and identity, are therapeutically  
3 equivalent and may be substituted for one another. Bioequivalence demonstrates that  
4 the active ingredient of the proposed generic drug is absorbed at the site of drug action  
5 to the same extent and for the same amount of time as the brand counterpart. 21  
6 U.S.C. § 355(j)(8)(B). Thus, a generic drug is identical to a brand name drug in  
7 dosage form, safety, strength, route of administration, and intended use.

8 36. Generic drugs that are therapeutically equivalent to their brand  
9 counterparts are given an “AB” rating by FDA, allowing their substitution for the  
10 brand when a prescription for the brand is presented at the pharmacy.

11 37. Congress enacted the Hatch-Waxman Amendments to expedite the entry  
12 of generic competitors, thereby reducing healthcare expenses nationwide. Congress  
13 also sought to protect pharmaceutical companies’ financial incentives to create new  
14 and innovative products.

15 38. The Hatch-Waxman Amendments achieved both goals, advancing  
16 substantially the rate of generic product launches, and ushering in an era of historic  
17 revenues for brand name pharmaceutical companies. In 1983, before the Hatch-  
18 Waxman Amendments, only 35% of the top-selling drugs with expired patents had  
19 generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for  
20 brand and generic drugs totaled \$21.6 billion, with generic drugs accounting for 18.6%  
21 of total prescriptions. By 2013, total prescription drug revenue had climbed to more  
22 than \$329.2 billion, with generic drugs accounting for 84% of prescriptions. *See* IMS  
23 INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF  
24 HEALTHCARE, at 30, 51 (Apr. 2014), *available at*  
25 <http://www.imshealth.com/cds/imshealth/Global/Content/>  
26  
27

Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI\_US\_Use\_of\_Meds\_for\_2013.pdf (last accessed June 2, 2014).

## 2. Paragraph IV Certifications

39. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book as claimed by the brand drug. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
- b. that the patent for the brand drug has expired (a "Paragraph II certification");
- c. that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or
- d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

40. If a generic manufacturer files a Paragraph IV certification that the listed patent is invalid or will not be infringed, it must promptly give notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement regardless of the merits of such an action. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, FDA may grant

1 “tentative approval,” but cannot grant final approval to authorize the generic  
2 manufacturer to go to market with its product. Accordingly, the timely filing of an  
3 infringement action provides the patent owner with the equivalent of an automatic  
4 preliminary injunction preventing final FDA approval of the challenged ANDA for up  
5 to 30 months, even if there is no merit to the infringement action.

6 41. As an incentive to spur generic companies to seek approval of generic  
7 alternatives to brand drugs, the first generic manufacturer to file an ANDA containing  
8 a Paragraph IV certification typically gets a period of protection from competition  
9 from other generic versions of the drug. The first generic applicant often receives 180  
10 days of market exclusivity, meaning that FDA will not approve any other ANDA for  
11 that same generic drug for at least six months. This allows the first filer to be free  
12 from competition from other generic companies for at least six months. However, the  
13 brand company is free to (and often does) launch its own “authorized generic” during  
14 the 180 day exclusivity period.

15 **B. Generic Versions of Brand Drugs are Significantly Less Expensive than**  
16 **Their Corresponding Brand Versions.**

17 42. Typically, AB-rated generics are priced significantly below their brand  
18 counterparts. “Although generic drugs are chemically identical to their branded  
19 counterparts, they are typically sold at substantial discounts from the branded price.  
20 According to the Congressional Budget Office, generic drugs save consumers an  
21 estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved  
22 when hospitals use generics.’” See [http://www.fda.gov/Drugs/](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm)  
23 [ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDr](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm)  
24 [ugs/ucm144456.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm).

1           **1. Generic Versions of Brand Drugs Quickly and Predictably Takes**  
 2           **Sales from Their Corresponding Brand Versions**

3           43. In every state, pharmacists are permitted (and in some states, required) to  
 4 substitute a generically-equivalent product for the brand product prescribed, unless the  
 5 doctor has indicated that the prescription for the brand product must be “dispensed as  
 6 written.” Because of the significant savings they allow and other institutional features  
 7 of the pharmaceutical industry, generic versions are substituted by pharmacists who  
 8 are presented with a prescription for the brand counterpart immediately upon launch of  
 9 the generic.

10          44. As more generic sellers enter the market, prices for generic versions of a  
 11 drug predictably decrease even further because of competition among the generic  
 12 sellers. Pharmacy substitution, and thus the loss of sales volume by the brand drug to  
 13 the corresponding generic, thereby accelerates. According to a recent FTC staff study,  
 14 within one year of generic entry, 90% of prescriptions are filled with the brand’s  
 15 generic substitute, and at prices that “are, on average, 85% lower than the pre-entry  
 16 branded drug price.” *“Pay for Delay: How Drug Company Pay-Offs Cost Consumers*  
 17 *Billions,”* FTC Staff, January 2010 at 8.

18          45. Generic competition enables all members of the proposed Class to:  
 19 (a) purchase generic versions of the drug at substantially lower prices; or (b) purchase  
 20 the brand drug at a reduced price.

21          46. Until a generic manufacturer enters the market, there is no generic drug to  
 22 substitute for and otherwise compete with the brand drug, thereby allowing the brand  
 23 manufacturer to continue to charge supracompetitive prices profitably, without losing  
 24 a substantial portion of its brand sales. Consequently, brand manufacturers have a  
 25 strong incentive to delay the introduction of generic competition into the market,  
 26 including paying generic companies to delay launching their generic products, such as  
 27

1 in this case. For Endo/Teikoku, that incentive was particularly strong: in 2012,  
2 Lidoderm accounted for 31% of Endo's revenues.

3 **2. No-Authorized-Generic Promises Are a Means By Which Brand**  
4 **Companies Pay Generic Companies to Delay Generic Competition**

5 47. One mechanism employed by brand companies to thwart generic  
6 competition is to make a payment to a first-filing generic company in the form of the  
7 brand company's promise not to launch an "authorized generic" version of the brand  
8 drug during the first 180 days of generic marketing (and sometimes longer). An  
9 authorized generic is the brand drug, manufactured just like the brand product, but  
10 sold as a generic product under the same approval as the brand product's original  
11 NDA. Because the brand manufacturer already has approval to sell its brand drug, it  
12 does not need to file an ANDA, or obtain any additional approval, to market an  
13 identical generic version of its own brand drug. ANDA filers have no patents on, and  
14 no right to be free from, an authorized generic version of the brand drug.

15 48. For the brand company, an authorized generic launched during the first  
16 180 days of generic marketing (or longer) provides a low cost, low risk means to  
17 regain some of the revenue lost from the termination of brand exclusivity. For the  
18 generic manufacturer enjoying exclusivity as the first generic to be marketed,  
19 however, an authorized generic launch has a huge negative impact on its revenue. A  
20 generic company generally earns about 80% of its total income from a given generic  
21 product during the period that it is the sole generic on the market. An authorized  
22 generic, when launched during that time, is typically priced competitively as against  
23 the other generics, and will capture 50% or more of total generic sales during that  
24 period. A brand's promise not to launch an authorized generic during the initial period  
25 of generic marketing is thus a very valuable payment to the generic company that is  
26 the first-filer generic entrant. It doubles the first-filer generic entrant's sales volume  
27 during that time, and, because it removes a source of price competition from the

1 market, it more than doubles the first-filer generic entrant's revenues and profits.  
2 Correspondingly, a brand's promise not to launch an authorized generic represents a  
3 substantial sacrifice of the revenues and profits that the authorized generic would  
4 otherwise have created for the brand. Those revenues and profits are instead ceded, by  
5 way of the no-authorized-generic promise, to the generic company.

6 49. In a report by the Federal Trade Commission ("FTC") issued at the  
7 request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects*  
8 *and Long-Term Impact* ("Authorized Generic Drugs"), the FTC concluded that no-  
9 authorized-generic promises are being used as a payment by brands to generics for  
10 delayed generic entry. The FTC analyzed documents and empirical data covering  
11 more than 100 companies and found that the presence of authorized generic  
12 competition reduces the first-filer generic's revenues by more than 50% during the  
13 first 180 days of generic marketing. *Authorized Generic Drugs* at iii, vi, 41-48, 57-59,  
14 available at [http://www.ftc.gov/sites/default/files/documents/reports/authorized-](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)  
15 [generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)  
16 [commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)  
17 [report-federal-trade-commission.pdf](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf).

18 50. The FTC found that a generic company makes significantly less money  
19 when it competes with an authorized generic because (1) the authorized generic takes  
20 a significant share of generic sales away from the first-filer (around 50%), and (2)  
21 wholesale and retail prices decrease when the first-filer faces an authorized generic  
22 due to competition between the two. Both of these factors reduce the generic  
23 company's sales and revenues. With a no-authorized-generic promise, the generic  
24 company avoids this reduction in revenue. The FTC noted that "there is strong  
25 evidence that agreements not to compete with an authorized generic have become a  
26 way for brand-name companies to compensate generic competitors for delaying entry.  
27

1 These agreements can be part of ‘pay-for-delay’ patent settlements, which have long  
2 concerned the Commission.” *See id.* at vi.

3 51. A 2006 study sponsored by the brand drug company trade association,  
4 PhRMA, similarly found that competition from an authorized generic results in lower  
5 generic prices.

6 52. An agreement between a brand and generic drug company — horizontal  
7 competitors — that the brand company will withhold an authorized generic from the  
8 market in exchange for the generic company’s agreement to delay market entry with  
9 its generic version of the brand drug, injures consumers twice over: first, by  
10 prolonging the period during which only the high-priced brand is available, and  
11 second, by ensuring that, once delayed generic competition begins, generic prices are  
12 artificially inflated because of the absence of the authorized generic.

13 53. For a first-filer generic like Watson, of a brand product like Lidoderm,  
14 the difference between (1) selling the only generic product and (2) selling a generic  
15 product while competing against an authorized generic, for the first months of generic  
16 marketing, constitutes a very large payment — reaching hundreds of millions of  
17 dollars. These economic realities are well known in the pharmaceutical industry, and  
18 the FTC’s authorized generic report cites numerous documents from industry  
19 participants confirming the financial impact of an authorized generic and, by  
20 necessary implication, its absence.

21 54. No-authorized-generic promises like the one Endo/Teikoku made as  
22 payment in exchange for Watson’s promise to delay introduction of generic Lidoderm  
23 thus allow horizontal competitors to benefit from an agreement not to compete and  
24 deny purchasers the consumer surplus that should flow to them from increased  
25 competition.

## VII. FACTUAL ALLEGATIONS

### A. Background

#### 1. Approval of Brand Lidoderm and its Purported Patent Protection

55. Lidoderm is a prescription lidocaine-containing patch approved to treat pain associated with post-herpetic neuralgia. The active ingredient in Lidoderm is 5% lidocaine. While other drugs are available to treat the same or similar medical conditions, they are not AB-rated to Lidoderm, cannot be automatically substituted for Lidoderm by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Lidoderm, and are not economic substitutes for, nor reasonably interchangeable with, Lidoderm.

##### a. Initial Approval of Lidoderm

56. On March 19, 1999, FDA approved NDA 200612, submitted by Hind Health Care, Inc. (“Hind”), which sought to market an adhesive patch containing 5% lidocaine under the brand name Lidoderm. Lidoderm was awarded Orphan Drug Exclusivity by FDA, meaning that no generic competitor could get FDA approval to market a generic Lidoderm product until March 2006.

57. In 1998, Hind granted to Endo the exclusive right to market and distribute Lidoderm in the United States. Hind subsequently transferred full ownership of and responsibility for the Lidoderm NDA to Teikoku, effective June 1, 1999. Teikoku then granted Endo the exclusive right to market and distribute the Lidoderm patch in the United States under Teikoku’s NDA, and Endo launched Lidoderm in the United States in 1999.

##### b. Endo/Teikoku’s Acquisition of Lidoderm Patents

58. Endo/Teikoku owned or obtained assignments of or licenses to a number of patents associated with Lidoderm. Subsequently, Teikoku listed several patents in the Orange Book as covering Lidoderm. As of January 2010 (after Watson had filed

1 ANDA No. 200675, the first ANDA filed as to Lidoderm), Teikoku had three patents  
2 listed in the Orange Book.

3 59. The first was U.S. Patent No. 5,411,738 (the “’738 patent”), which is a  
4 method of use patent for treating certain types of pain with lidocaine using a topical  
5 delivery mechanism and a gel formulation of lidocaine. The second was U.S. Patent  
6 No. 5,601,838 (“the ’838 patent”), which is a method of use patent for treating certain  
7 types of pain with lidocaine. The ’738 and ’838 patents both were assigned to Hind,  
8 both expired on May 2, 2012, and are referred to collectively as the “Hind patents.”

9 60. The third patent that Teikoku listed in the Orange Book as covering  
10 Lidoderm was U.S. Patent No. 5,827,529 (the “’529 patent”), which is a formulation  
11 patent for a lidocaine patch. This patent was assigned to Teikoku, and is set to expire  
12 on October 17, 2015. Endo is the exclusive licensee of the ’529 patent.

13 61. The ’529 patent, titled “External Preparation for Application to the Skin  
14 Containing Lidocaine,” issued on October 27, 1998, from an application filed on June  
15 10, 1994. That application was a continuation of an application filed on March 30,  
16 1992.

17 62. The ’529 patent claims foreign priority to Japanese Application No. 3-  
18 067353, filed March 30, 1991.

19 63. The ’529 patent contains six claims directed generally to a hydrogel  
20 transdermal patch containing the active ingredient lidocaine and inactive ingredients  
21 or excipients.

22 64. Claim 1 of the ’529 patent claims a patch comprising “a drug-retaining  
23 layer placed on a support,” in which the drug-retaining layer comprises an “adhesive  
24 gel base and 1 to 10% by weight of lidocaine.” The claimed “adhesive gel base”  
25 consists of three components within specific percentage weight ranges: (i) “0.5 to  
26

1 50% by weight of a water-soluble high molecular weight substance”; (ii) “30 to 70%  
2 by weight of water”; and (iii) “1 to 70% by weight of a water-retaining agent.”

3 **c. Endo/Teikoku Seek to Bolster Lidoderm’s Patent Coverage**

4 65. Endo subsequently obtained additional patents from LecTec Corporation  
5 (“LecTec”) that it and Teikoku claim cover Lidoderm. In July 2008, LecTec had filed  
6 patent infringement litigation against Endo and other manufacturers of medicinal  
7 patch products in the United States District Court for the Eastern District of Texas (the  
8 “LecTec Litigation”) over U.S. Patent No. 5,536,263 (the “’263 patent”), and U.S.  
9 Patent No. 5,741,510 (the “’510 patent”), both of which are patents for a medicinal  
10 adhesive patch. Each of these patents expired on March 30, 2014.

11 66. Endo settled the litigation with LecTec in November 2009, paying  
12 LecTec \$23 million in exchange for exclusive licenses to the ’263 and the ’510 patents  
13 for use in the field of prescription pain medications and treatment.

14 67. Almost a year later, in or about October 2010, Endo granted Teikoku a  
15 sublicense under the ’510 patent to make and sell prescription pain medications that  
16 contain 5% lidocaine in patch dosage form, including Lidoderm.

17 68. In or about November 2010, Teikoku submitted the ’510 patent to FDA  
18 for listing in the Orange Book with respect to Lidoderm.

19 69. As of January 2011, Endo/Teikoku had four patents listed in the Orange  
20 Book related to Lidoderm: the two Hind patents (which expired in May 2012), the  
21 ’529 patent, and the ’510 patent.

22 70. In or about May 2011, in exchange for \$2 million, Endo acquired from  
23 LecTec full title to the ’263 patent, the ’510 patent and three other patents. The three  
24 other patents were U.S. Patent No. 6,096,333 (the “’333 patent”), (ii) U.S. Patent No.  
25 6,096,334 (the “’334 patent”); and (iii) U.S. Patent No. 6,361,790 (the “’790 patent”)  
26 (collectively with the ’263 and the ’510 patents, “the Rolf patents,” named for one of  
27

1 the inventors). These three patents all cover methods of formulating a medicinal  
2 adhesive patch and expired on March 30, 2014. Other than the '510 patent, none of  
3 the Rolf patents was listed in the Orange Book with respect to Lidoderm.

4 **2. Watson's ANDA Threatens Endo/Teikoku's Weak Patents**

5 71. On November 13, 2009, Watson submitted ANDA No. 200675 to FDA,  
6 seeking to market a generic version of Lidoderm. On or about January 14, 2010,  
7 Watson notified Teikoku of its November 13, 2009 ANDA filing.

8 72. Watson's notice letter included a Paragraph IV certification that the  
9 commercial manufacture, use and/or sale of its generic Lidoderm product would not  
10 infringe any claim of the '529 patent, and/or that the '529 patent was invalid and/or  
11 unenforceable. Watson was the first generic manufacturer to file an ANDA with a  
12 Paragraph IV certification with respect to Lidoderm, potentially entitling it to a six-  
13 month exclusivity period, free from competition from any other ANDA-filing generic  
14 company. This exclusivity, however, would not have protected Watson from  
15 competition from an authorized generic version of Lidoderm.

16 73. Watson did not submit Paragraph IV certifications as to the Hind patents,  
17 which were to expire on May 2, 2012. As a result, FDA could not approve Watson's  
18 ANDA for generic Lidoderm until the Hind patents expired on May 2, 2012.

19 74. Watson made no certification to any of the Rolf patents because the Rolf  
20 patents were not listed in the Orange Book until November 2010, a year after Watson  
21 filed its ANDA.

22 75. FDA granted final approval to Watson's ANDA on August 23, 2012, but  
23 Watson did not launch its approved generic Lidoderm product until September 16,  
24 2013, because of the unlawful Reverse Payment Agreement with Endo/Teikoku. No  
25 patents asserted, or capable of being asserted, by Endo/Teikoku would or could have  
26 prevented Watson from launching its approved generic Lidoderm product.

1                   **3.     Endo and Teikoku Scramble to Protect Their Franchise**

2           76.     On February 19, 2010, Endo/Teikoku sued Watson in the United States  
3 District Court for the District of Delaware (*Endo Pharm. Inc., et al., v. Watson Labs.,*  
4 *Inc.*, Civil Action No. 10-cv-00138-GMS), alleging that Watson's generic Lidoderm  
5 infringed the '529 patent (the "'529 Litigation"). As a result of the filing of the '529  
6 Litigation, a 30-month Hatch-Waxman stay of FDA approval applied to Watson's  
7 ANDA, which precluded FDA from approving Watson's ANDA until (i) that stay  
8 expired in mid-July of 2012, or (ii) entry of a final judgment that the '529 patent was  
9 invalid, unenforceable, and/or not infringed.

10           77.     Watson raised numerous defenses, including that the '529 patent was  
11 invalid and/or unenforceable.

12           78.     As the '529 Litigation moved toward trial, Endo/Teikoku filed yet  
13 another suit against Watson, this time using the Rolf patents. On or about June 29,  
14 2011, Endo filed suit against Watson in the United States District Court for the District  
15 of Delaware (*Endo Pharm. Inc. v. Watson Labs., Inc.*, Civil Action No. 11-cv-00575-  
16 GMS) (the "Rolf Patent Litigation"), alleging that Watson's generic Lidoderm product  
17 would infringe three of the Rolf patents – the '333 patent, the '334 patent, and the  
18 '510 patent. Only the '510 patent had been listed in the Orange Book. Because the  
19 Rolf patents had not been listed in the Orange Book when Watson filed its ANDA, the  
20 Rolf Patent litigation did not result in a 30-month Hatch-Waxman stay.

21                   **a.     The '529 Litigation Exposed the Weakness of Endo/Teikoku's**  
22                   **'529 Patent**

23           79.     After the June 27, 2011 *Markman* hearing in the '529 Litigation, Judge  
24 Sleet rejected Endo's claim construction position, strengthening Watson's defense to  
25 Endo/Teikoku's infringement claims. The '529 Litigation then proceeded to a bench  
26 trial in February 2012, in which Watson presented evidence of the invalidity of the  
27 '529 patent, as well as evidence that Watson's generic did not infringe the patent. The

evidence at trial was overwhelmingly in favor of Watson, exposing the '529 patent to a determination that it was invalid or unenforceable and that the patent did not cover either the brand product or Watson's generic product.

**(1) The '529 Patent Was Invalid**

80. The evidence developed during the '529 Litigation revealed that the same hydrogel transdermal patch technology claimed in the '529 patent had previously been disclosed in multiple pieces of prior art that were not disclosed to the patent examiner, but were well known to Endo/Teikoku (the "Teikoku Prior Art"). Each of the pieces of Teikoku Prior Art discloses a hydrogel transdermal patch formulation substantially similar to that claimed in the '529 patent.

81. Each piece of the Teikoku Prior Art discloses an "adhesive gel base" consisting of (i) a water-soluble high molecular weight substance; (ii) water; and (iii) a water-retaining agent, all of which fall within the percentage ranges claimed in the '529 patent. Each shares at least one inventor with the '529 patent, and also shares the same applicant, prosecuting attorneys, or assignee with the '529 patent.

82. During the prosecution of the '529 patent, the PTO rejected the patent four times, noting that because lidocaine was conventionally used in transdermal patches, it would have been obvious to place lidocaine into available prior art patches. The applicants consistently distinguished other prior art patches cited by the Examiner, arguing that the patch in the '529 patent was "unique." The applicants never disclosed the Teikoku Prior Art to the PTO, or a prior art patent with the same elements as the '529 patent, which would have showed that the patch technology in the '529 patent was not unique, and in fact had been previously patented. The PTO never cited the Teikoku Prior Art.

83. Each of these prior art references is prior art to the '529 patent because each was publicly available and accessible more than one year before the March 30,

1 1991 priority date of the '529 patent. Each of the prior art references predates the  
2 priority date of the '529 patent by over a year, and thus invalidates the '529 patent.  
3 The '529 patent was not capable of preventing Watson from launching its approved  
4 generic Lidoderm product.

5 **(2) The '529 Patent Was Not Infringed**

6 84. In addition to being invalid, the '529 patent did not cover Lidoderm and  
7 was not infringed by Watson's generic equivalent. The patch formulation disclosed in  
8 the '529 patent included a water-soluble high-molecular-weight substance, water, and  
9 a water-retaining agent. The water-soluble high-molecular-weight substance and the  
10 water-retaining agent must be from the groups listed in the patent. The groups listed  
11 in the '529 patent are known as Markush groups. "A Markush group is a listing of  
12 specified alternatives of a group in a patent claim, typically expressed in the form: a  
13 member selected from the group consisting of A, B, and C." *Endo Pharm. Inc., et al.,*  
14 *v. Watson Labs., Inc.*, slip op. at 1 n.1, No. 10-138 (GMS) (D. Del. June 27, 2011)  
15 (*quoting Abbott Labs. v. Baxter Pharm. Prods.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003)).

16 85. In the '529 patent, the first Markush group related to "a water-soluble  
17 high molecular weight substance selected from the group consisting of gelatin, starch,  
18 agar, mannan, alginic acid, polyacrylic acid, a salt of polyacrylic acid, dextrin,  
19 methylcellulose, methylcellulose sodium, carboxymethylcellulose,  
20 carboxymethylcellulose sodium, polyvinyl alcohol, polyvinyl pyrrolidone, copolymer  
21 of methyl vinyl ether and maleic anhydride, gum arabic, tragacanth, karaya gum and  
22 locust bean gum."

23 86. The second Markush group related to "a water-retaining agent selected  
24 from the group consisting of ethylene glycol, diethylene glycol, polyethylene glycol,  
25 glycerin, sorbitol, martitol, propylene glycol and 1,3-butylene glycol."

1           87. As the District Court held in its *Markman* decision construing those two  
2 patent terms, Federal Circuit precedent from 2003 clearly established that both of the  
3 relevant Markush groups in the '529 patent were limited to one and only one of the  
4 listed alternatives. *Endo Pharm. Inc., et al., v. Watson Lab., Inc.*, slip op. at 1 n.1-2.  
5 Under Federal Circuit precedent, the patent must be interpreted to cover a product  
6 which contains only *one* of the substances from each of the two Markush groups.

7           88. Watson's generic Lidoderm product contained at least *four* water-soluble  
8 high-molecular-weight substances, and *three* water-retaining agents. (So does  
9 Lidoderm.) Thus, it did not infringe the '529 patent because it contained more than  
10 one substance from each Markush group. As a result, Watson's generic Lidoderm  
11 product did not infringe the '529 patent. The '529 patent was not capable of  
12 preventing Watson from launching its approved generic Lidoderm product.

13                   **b. The Rolf Patent Litigation**

14           89. The Rolf patents afforded Endo/Teikoku no basis to prevent Watson from  
15 launching its approved generic Lidoderm product, either. Endo/Teikoku sued Watson  
16 only on some of the Rolf patents (the '510, '333, and '334 patents). Watson had  
17 raised defenses and counterclaims alleging those patents were invalid and/or  
18 unenforceable and that its product did not infringe them. Endo/Teikoku did not even  
19 bother to sue Watson on the '263 patent. The Rolf Patent Litigation barely proceeded  
20 past the pleading stage. The Rolf patents posed no reasonable risk to Watson of patent  
21 infringement liability.

22           90. Of the Rolf patents, only the '510 patent had been asserted by its previous  
23 owner, LecTec, against Endo with respect to its Lidoderm product in the LecTec  
24 Litigation in 2008. As Endo/Teikoku learned from the LecTec Litigation, the '510  
25 patent was subject to a strong invalidity challenge. The '510 patent was invalid as  
26 obvious in view of prior art references that were not submitted to the PTO during the  
27

1 prosecution of the '510 patent. Watson, too, was aware of the infirmities of the '510  
2 patent from the publicly filed pleadings in the LecTec Litigation. The '510 patent was  
3 incapable of preventing Watson from launching its approved generic Lidoderm  
4 product.

5 91. The '333 and '334 patents were also not infringed by Watson. Indeed,  
6 during the LecTec litigation, LecTec had not even sued Endo for infringement of the  
7 '333 and '334 patents with respect to Lidoderm. When Endo ultimately settled the  
8 LecTec Litigation in November 2009, it obtained licenses only to the '263 and '510  
9 patents, further demonstrating that licenses to the '333 and '334 patents were  
10 irrelevant to the use, manufacture, or sale of Lidoderm. Watson's generic patch, a  
11 copy of the Endo patch, similarly would not infringe the '333 and '334 patents.

12 92. Indeed, Endo did not bother to obtain the rights to the '333 and '334  
13 patents until May 2011, when it bought the rights to all of the Rolf patents from  
14 LecTec for just \$2 million, still further evidence that those patents were incapable of  
15 preventing Watson from launching its approved generic Lidoderm product. None of  
16 the Rolf patents was capable of preventing Watson from launching its approved  
17 generic Lidoderm product.

18 **B. Endo/Teikoku and Watson Enter the Unlawful Reverse Payment**  
19 **Agreement**

20 93. On or about May 28, 2012 — after the February 2012 bench trial and as  
21 Endo/Teikoku and Watson were awaiting a decision from Judge Sleet —  
22 Endo/Teikoku and Watson entered into an agreement ending the patent litigation  
23 related to Lidoderm. The Reverse Payment Agreement ended the '529 Litigation and  
24 the Rolf Patent Litigation, and obviated the need for Judge Sleet to render decisions on  
25 the validity, enforceability, and infringement of the patents Endo/Teikoku had asserted  
26 against Watson.

94. Under the Agreement, Watson agreed to delay launching its generic Lidoderm product until a “Start Date” of September 15, 2013 unless before that date another generic product launched (a virtual impossibility) or Watson faced forfeiture of its 180-day exclusivity for failing to go to market (also a virtual impossibility). The Agreement specifically provides:

Subject to Section 2(d), Watson agrees, on behalf of itself and its Affiliates, that, prior to the Start Date, it and its Affiliates shall not directly or indirectly market, offer to sell, sell, have sold, import, manufacture or have manufactured in the Territory any of Watson’s Generic Product. Watson acknowledges and agrees that each of Endo and Teikoku would be irreparably harmed should Watson breach this Section 2(e). Nothing in this Agreement shall prohibit or preclude Watson from exercising its rights under 35 U.S.C. § 271(e)(1). [Settlement Agreement at Section 2(e).]

\*\*\*

“Start Date” means the earliest of: (i) September 15, 2013; (ii) the date of Launch of any Generic Product other than Watson’s Generic Product; or (iii) the last day before Watson would forfeit its 180-day generic drug exclusivity with respect to Watson’s Generic Product due to the operation of 21 U.S.C. 355(j)(5)(D)(ii) as a result of a forfeiture event under 21 U.S.C. 355(j)(5)(D)(i)(I). [*Id.* at Section 1(v).]

95. As one *quid pro quo* for Watson’s promise to delay entry of its generic Lidoderm product until September 15, 2013, Endo/Teikoku promised to share with Watson the monopoly profits they would reap from Lidoderm’s extended market exclusivity by paying Watson at least \$96 million (in the form of brand Lidoderm provided by Endo/Teikoku at no cost to Watson) at the rate of \$12 million per month from January 1, 2013 through August 1, 2013. Watson was free to sell the brand Lidoderm product and retain the full proceeds of those sales. This payment was no different than if Endo/Teikoku had made those sales themselves and paid Watson the resulting \$96 million in cash. The Agreement specifically provides:

Endo/Teikoku shall provide, at no cost, to Watson’s Wholesaler Affiliate Brand Product of value totaling twelve million dollars (\$12,000,000) per month, as measured at the time of each delivery by the then-prevailing Wholesale Acquisition Cost as defined in the Red Book or, if the Red Book is not available, any other comparable U.S. price listing (“WAC”), on the first business day of each month beginning January 1, 2013 and ending August 1, 2013 (for a total of eight (8) months) for Watson’s Wholesaler Affiliate’s disposal as provided in Section 3(e). Endo shall

- 27 -

provide to Watson's Wholesaler Affiliate an invoice with respect to such Brand Product, which invoice shall reflect the transfer of Brand Product to Watson's Wholesaler Affiliate at no cost. Notwithstanding the foregoing, Endo/Teikoku's obligations under this Section 3(b) shall terminate immediately upon the Launch of any Third Party Generic Product in the Territory. The Brand Product provided to Watson's Wholesaler Affiliate by Endo/Teikoku shall have the same NDC number as the Brand Product sold by Endo. In any month in which Endo/Teikoku has provided to Watson's Wholesaler Affiliate any Brand Product under this Section 3(b), and in which a Third Party has Launched a Generic Product in the Territory, Watson shall either (i) return to Endo a pro rata quantity of the Brand Product delivered by Endo/Teikoku during such month, or (ii) reimburse Endo in cash for the value of the Brand Product (based on the WAC measured at the time of delivery by Endo/Teikoku to Watson's Wholesaler Affiliate), in either case for the pro rata portion of the month on and after such Launch[.] \* \* \* Such return or reimbursement shall be made by Watson to Endo within five (5) business days of the date of the Launch of a Generic Product in the Territory. [Settlement Agreement at Section 3(b) (emphasis added).]

\*\*\*

The Brand Product supplied by Endo/Teikoku to Watson's Wholesaler Affiliate under Sections 3(b) through (d) may be resold solely by Watson's Wholesaler Affiliate to Third Parties for use solely in the Territory on pricing and other terms determined by Watson's Wholesaler Affiliate in its sole discretion, provided that neither Watson nor any of its Affiliates (including its Wholesaler Affiliate) shall sell, distribute or dispose of Branded Product in any manner that would constitute a Bundled Sale. Watson agrees that its Wholesaler Affiliate will honor all Endo price-related contracts as communicated to all Endo wholesalers from time to time in the ordinary course of business, provided that the price related contracts do not impose any requirements on Watson's Wholesaler Affiliate that would be inconsistent with requirements imposed upon other Lidoderm® wholesalers, and further provided that such price-related contracts shall not conflict with the terms of this Agreement. Watson shall comply with all Applicable Laws in connection with its resale of the Brand Product. [Settlement Agreement at Section 3(e).]

96. Endo/Teikoku also agreed to make additional payments to Watson if Watson did not receive FDA approval for its generic Lidoderm product by January 1, 2014, as well as additional payments if Watson did not receive approval by January 1, 2015. Neither situation came to pass or was expected to come to pass: Watson received final FDA approval on August 23, 2012, within three (3) months of Defendants' execution of the Reverse Payment Agreement.

1           97. As the Agreement expressly provided, this \$96 million payment from  
2 Endo/Teikoku to Watson was expressly to induce Watson to quit its challenge to  
3 Endo/Teikoku's patents:

4           Endo/Teikoku and Watson agree that the Brand Product provided by  
5 Endo/Teikoku to Watson's Wholesaler Affiliate hereunder is a good-  
6 faith, bargained-for resolution of the claims at issue in the Litigation. The  
7 Brand Product provided hereunder is not contingent on any past or future  
8 purchase of any product from Endo or Teikoku by Watson or any of its  
9 Affiliates. [Agreement, Section 3(i).]

10           98. Through the Agreement, Defendants ensured that Watson's sales of  
11 Lidoderm would not result in price competition, but rather that Watson would sell  
12 brand Lidoderm at the same supracompetitive prices at which Endo had been selling  
13 it. The Agreement provided that Watson would honor all of Endo's price-related  
14 contracts honored by Endo's wholesalers. In fact, Watson maintained the  
15 supracompetitive prices for brand Lidoderm throughout the term of the Agreement,  
16 generating revenues and profits of close to \$96 million from those sales. Watson's  
17 sales of branded Lidoderm did not increase output, reduce price, or increase consumer  
18 choice; it merely substituted Watson for Endo/Teikoku as the seller of \$96 million  
19 worth of branded Lidoderm, solely to pay Watson for delaying market entry of its less-  
20 expensive generic Lidoderm.

21           99. As a second payment in exchange for Watson's promise to delay entry of  
22 its generic Lidoderm product until September 15, 2013, Endo/Teikoku promised to  
23 delay launching an authorized generic version of Lidoderm for 7½ months after  
24 Watson's belated launch of generic Lidoderm, unless another ANDA filer entered the  
25 market during that time (a virtual impossibility that, in fact, did not occur).

26           100. Endo/Teikoku were otherwise ready, willing, and able to launch an  
27 authorized generic version of Lidoderm simultaneously with Watson's launch. As  
28 early as April 2007, Endo and Teikoku had specifically agreed that Endo would be the  
exclusive licensee for authorized generic Lidoderm. As shown below, this no-

1 authorized-generic promise effectuated a payment from Endo/Teikoku to Watson of  
2 \$170 million or more.

3 101. Endo/Teikoku's agreement not to launch an authorized generic meant that  
4 Endo/Teikoku would cede those sales to Watson, and Watson would therefore be the  
5 sole generic on the market for 7½ months. This would allow Watson to obtain 100%  
6 of generic Lidoderm sales for 7½ months (instead of just 50% if Endo/Teikoku had  
7 launched an authorized generic) and additionally permitted Watson to avoid the inter-  
8 generic price competition an authorized generic necessarily creates and thereby  
9 maintain an artificially-inflated supracompetitive generic price for those doubled  
10 generic sales. These doubled revenues and profits were at the expense of Plaintiffs  
11 and the members of the Class, consumers, and competition in general. The Agreement  
12 (which refers to an authorized generic by the acronym "AG") provides:

13 License. Subject to the terms and conditions of this Agreement,  
14 Endo/Teikoku hereby grant to Watson a non-exclusive (other than  
15 pursuant to Section 2(b)), royalty-bearing, non-transferable (other than  
16 pursuant to Section 21) and non-sublicensable (other than pursuant to  
Section 2(c)) license to the Licensed Patents to make, have made, import,  
use, sell, and offer for sale Watson's Generic product in the Territory  
solely during the License Term. [Settlement Agreement at Section 2(a).]  
\*\*\*\*\*

17 AG Product. The license granted pursuant to Section 2(a) shall be  
18 partially exclusive for a period of time in that Endo/Teikoku and their  
19 respective Affiliates shall not market or sell a Generic Product, or  
20 authorize or license a Third Party to market or sell and AG Product at any  
time before the earlier of (i) seven and a half (7.5) months from the Start  
Date, and (ii) the Launch of any Third Party Generic Product in the  
Territory. [Settlement Agreement at Section 2(b) (emphasis added).]

21 102. Endo/Teikoku's agreement not to launch an authorized generic for 7½  
22 months allowed Watson to double its generic sales *and* charge higher prices for its  
23 generic during that time (because it faced no competition from an authorized generic),  
24 and had a cash value to Watson of \$170 million or more. Endo/Teikoku's no-  
25 authorized-generic promise is little different than if Endo/Teikoku actually did launch  
26 an authorized generic alongside Watson during the first 7½ months that Watson  
27

1 marketed generic Lidoderm, and simply handed the proceeds from those sales over to  
2 Watson in cash. (Though Endo/Teikoku would have to give Watson additional  
3 monies on top of those revenues, to make up for the higher price Watson's generic  
4 Lidoderm would have been able to command because it was free from price  
5 competition from Endo/Teikoku's authorized generic).

6 103. Absent the Reverse Payment Agreement, and Endo/Teikoku's promise  
7 not to launch an authorized generic contained therein, Endo/Teikoku would have  
8 launched an authorized generic simultaneously with Watson's entry, which would  
9 have resulted in lower prices to Plaintiffs and the Class, and cut Watson's revenues  
10 and profits from selling generic Lidoderm by half.

11 104. In fact, at their first opportunity following the expiration of the no-  
12 authorized-generic promise, Endo/Teikoku immediately launched an authorized  
13 generic.

14 105. The Reverse Payment Agreement contained a term whereby Watson  
15 agreed to pay back to Endo/Teikoku a small (25%) portion of Watson's increased  
16 profits resulting from Endo/Teikoku's agreement not to launch an authorized generic  
17 for 7½ months. That term provided: "Beginning with the First Commercial Sale of  
18 Watson's Generic Product and until the date of the occurrence of the First Commercial  
19 Sale by a Third Party or Endo/Teikoku or their Affiliates of a Generic Product or AG  
20 Product in the Territory, Watson shall pay to Endo royalty payments equal to twenty-  
21 five percent (25%) of all Gross Profit of Watson's Generic Product." Agreement,  
22 Section 3(a).

23 106. This term providing for a 25% royalty back to Endo/Teikoku during the  
24 7½ month period was window dressing for the parties' naked agreement not to  
25 compete during Watson's anticipated 180-day Hatch-Waxman exclusivity period. The  
26 royalty was designed merely to give the appearance of a legitimate, non-collusive  
27

1 transaction. In reality, Defendants simply agreed to lengthen the no-authorized-  
2 generic promise's duration by 1½ months (from 6 months to 7½ months) in order to  
3 mitigate the royalty Watson would be paying to Endo/Teikoku.

4 107. Plaintiffs' estimate that Endo/Teikoku's payment to Watson by the no-  
5 authorized-generic promise amounted to \$170 million or more already accounts for an  
6 assumed 25% royalty paid by Watson back to Endo/Teikoku.

7 108. Endo/Teikoku sacrificed substantial revenues and profits by their  
8 agreement not to launch an authorized generic for 7½ months. Absent the Reverse  
9 Payment Agreement and the delay in generic Lidoderm competition it effectuated, it  
10 would have made economic sense for Endo/Teikoku to launch an authorized generic  
11 simultaneous with Watson's launch so that Endo/Teikoku could retain sales that  
12 Watson's less expensive generic otherwise would capture, rather than ceding those  
13 sales to Watson. As alleged above, an authorized generic product typically captures  
14 approximately 50% of the generic sales during first 180 days of generic marketing.

15 109. The no-authorized-generic promise was a very large payment to Watson.  
16 Using a conservative approach that relies upon the revenue numbers that Endo  
17 reported in its filings with the Securities and Exchange Commission as an input for the  
18 annual revenue from Lidoderm, and valued as of the time the Reverse Payment  
19 Agreement was entered, Plaintiffs estimate that the no-authorized-generic promise  
20 constituted a payment of \$170 million or more from Endo/Teikoku to Watson. This  
21 figure is estimated by calculating the difference between Watson's revenues during the  
22 7½ months free from competition from Endo/Teikoku's authorized generic and  
23 Watson's revenues during 7½ months facing competition from Endo/Teikoku's  
24 authorized generic. Both of these amounts can be estimated using the known  
25 dynamics of the pharmaceutical industry and publicly-available information.  
26  
27

110. The amount of revenue Watson would expect to earn from sales of generic Lidoderm during the first 7½ months of marketing free from competition from Endo/Teikoku's authorized generic can be estimated as follows:

- a. At the time Defendants entered the Agreement, Endo had reported that its annual revenue from sales of Lidoderm in the prior year, 2011, was \$825 million. Thus, at the time of the Agreement, 7½ months of branded Lidoderm sales would generate revenue to Endo/Teikoku of at least \$515,625,000 ( $7.5/12 * 825,000,000$ ).<sup>1</sup>
- b. As is common in the pharmaceutical industry, the first generic is expected to take 80% (or more) of the brand's unit sales within six months. Thus, approximately \$412,500,000 worth of brand unit sales would be converted to Watson's generic during the first 7½ months Watson's generic Lidoderm was on the market ( $515,625,000 * .8$ ).
- c. As is also common, with only one generic on the market, the generic is typically priced at 90% of the brand's pre-generic price, which would result in generic sales revenues during the first 7½ months Watson was on the market of approximately \$371,250,000 ( $412,500,000 * .9$ ). Thus, the sales revenues Watson would have obtained during the 7½ months that the no-authorized-generic promise was in effect were approximately \$371,250,000.
- d. Under the Agreement, Watson agreed to pay Endo/Teikoku a royalty of 25% on Watson's gross profits on sales of generic versions of Lidoderm during the 7½ month period that the no-authorized-generic

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<sup>1</sup> That number is conservative, as it does not account for any increase in sales achieved by Endo/Teikoku in 2012 and 2013, during the period of delayed generic Lidoderm competition purchased by Endo/Teikoku's payments to Watson. In fact, Endo/Teikoku's Lidoderm revenue rose from \$825 million in 2011 to \$947 million in 2012.

promise was in effect. Conservatively applying the royalty on \$371,250,000 in sales (as opposed to the lower number that would reflect Watson's gross profits), and further assuming that royalties were actually paid, this would amount to approximately \$92,812,500 ( $371,250,000 * .25$ ). As a result, even when the amount of the royalty is netted out, Watson's anticipated revenue during 7½ months free from competition from Endo/Teikoku's authorized generic would be, conservatively, \$278,437,500 ( $371,250,000 - 92,812,500$ ).

111. Watson's dramatically smaller revenues if Endo/Teikoku had not promised to refrain from launching an authorized generic for 7½ months following Watson's launch can be estimated as follows:

- a. According to an FDA study of the dynamics of generic competition, the addition of a second generic (such as Endo/Teikoku's authorized generic) drives the average generic price down to 52% of the brand price.<sup>2</sup> Thus, while the generics would still take 80% of brand sales during those first 7½ months, or \$412,500,000 at the branded Lidoderm price, the dollar value of those generic sales would drop to \$214,500,000 in the presence of an authorized generic ( $412,500,000 * .52$ ).
- b. Watson would not get 100% of those revenues, however. That is because the unit sales of the generic during those first 7½ months would be split evenly between Watson's generic Lidoderm and

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<sup>2</sup> Generic Competition and Drug Prices, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (last accessed June 3, 2014).

1                   Endo/Teikoku's authorized generic Lidoderm.<sup>3</sup> (Moreover, there is  
 2                   reason to expect that Endo/Teikoku may have enjoyed a marketing  
 3                   advantage as the incumbent and garner more than 50% of unit sales.)  
 4                   c. Thus, without Endo/Teikoku's no-authorized-generic promise,  
 5                   Watson's revenues from sales of generic Lidoderm during the first 7½  
 6                   months of generic marketing would have been approximately  
 7                   \$107,250,000 (214,500,000 \* .5).

8                   112. The incremental revenue that Endo/Teikoku paid to Watson by the no-  
 9                   authorized-generic promise is therefore \$171,187,500 (278,437,500 - 107,250,000).  
 10                  That amount is the payment that Endo/Teikoku made to Watson by way of the no-  
 11                  authorized-generic promise contained in the Reverse Payment Agreement. This  
 12                  estimate assumes that, rather than Defendants' entering an agreement that allowed  
 13                  Watson to enter without Endo/Teikoku paying Watson to delay its entry, Watson  
 14                  would have entered the market "at risk" in the "but-for world" (*i.e.*, in a world absent  
 15                  the reverse payments challenged by this lawsuit).

16                  113. By contrast, had the parties instead entered an agreement without  
 17                  Endo/Teikoku paying Watson to delay entry of its generic Lidoderm, and the  
 18                  Agreement consequently bore an earlier agreed entry date, and assuming a term in that  
 19                  agreement requiring Watson to pay a royalty of 25% during the first 7½ months of  
 20                  Watson's generic marketing, the royalty on those sales would be \$26,812,500  
 21                  (107,250,000 \* .25). Thus, net of royalties, the revenue Watson would have realized  
 22                  during the first 7½ months of marketing from an earlier licensed entry with  
 23

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24                  <sup>3</sup> *Id.* at vi (The Federal Trade Commission has concluded that, when free from  
 25                  competition from an authorized generic, "the first-filer's revenue will approximately  
 26                  double" during the first six months of generic competition, compared to what the first  
 27                  filer would make if it faced authorized generic competition.). The Supreme Court has  
 recognized this as well. *See FTC v. Actavis*, 133 S. Ct. 2223, 2229 (2013) (the "vast  
 majority of potential profits for a generic drug manufacturer materialize during" the  
 first six months of marketing).

1 competition from Endo/Teikoku's authorized generic would be \$80,437,500  
2 (107,250,000 - 26,812,500).

3 114. The incremental revenue that Endo/Teikoku paid to Watson by the no-  
4 authorized-generic promise is therefore approximately \$198,000,000 (278,437,500 –  
5 80,437,500). That amount is the payment that Endo/Teikoku made to Watson by way  
6 of the no-authorized-generic promise contained in the Reverse Payment Agreement.  
7 This second estimate assumes that, rather than Watson entering the market at risk,  
8 Defendants enter into an agreement that allowed Watson to enter without  
9 Endo/Teikoku paying Watson to delay its entry in the “but-for world” (*i.e.*, in a world  
10 absent the reverse payments challenged by this lawsuit).

11 115. Thus, Endo/Teikoku's agreement not to launch an authorized generic  
12 version of Lidoderm for 7½ months was a payment to Watson of at least \$170 million  
13 and possibly \$198 million or more. The value of this payment to Watson was no  
14 different than if Endo had made those sales itself (by launching an authorized generic)  
15 and then handed the resulting \$170-198 million or more to Watson in cash. And,  
16 given that Lidoderm revenues increased significantly to \$947 million in 2012, the size  
17 of the payment almost certainly increased by the time Watson ultimately received it in  
18 September of 2013, when Watson belatedly launched without competition from  
19 Endo/Teikoku's authorized generic.

20 116. The total payment flowing from Endo/Teikoku to Watson, including  
21 both the \$96 million in free goods and Endo/Teikoku's promise to delay launching an  
22 authorized generic version of Lidoderm for 7½ months had a cash value in the  
23 hundreds of millions of dollars. Although Plaintiffs do not assume the burdens of  
24 production or proof on Defendants' affirmative defenses by so doing, Plaintiffs  
25 nevertheless aver that Defendants can offer no cognizable, nonpretextual justification  
26 or explanation for the reverse payments. The reverse payments are far greater than  
27

1 Endo/Teikoku's avoided litigation costs, and were not for services to be provided by  
2 Watson to Endo/Teikoku. Rather, the reverse payments were made in order to induce  
3 Watson to stay out of the lidocaine patch 5% market until September of 2013 and to  
4 allow Defendants to share monopoly profits.

5 117. These large, unjustified payments have no rational connection to, and far  
6 exceed, any approximation of the costs of continuing the patent litigation. Moreover,  
7 Defendants are unable to establish that either payment was consideration for the fair  
8 value of any services provided by Watson to Endo/Teikoku. Indeed, Watson was not  
9 required to perform any services in exchange for the unlawful payment according to  
10 the Reverse Payment Agreement. Watson provided no value to Endo/Teikoku under  
11 the Agreement other than impermissible agreement to delay competition. The  
12 Agreement was not a distribution agreement, and Endo had no need for any such  
13 services for Lidoderm in any event.

14 118. Absent Endo/Teikoku's unlawful reverse payments to Watson, any  
15 agreement settling the patent litigation would have resulted in much less delay of  
16 Watson's generic entry than with the payments. But for the reverse payments, Watson  
17 would have launched much earlier than September 2013, either under an agreement  
18 without any reverse payments, or at risk after final approval. And, in either  
19 circumstance, Watson's entry would have been immediately met with Endo/Teikoku's  
20 authorized generic.

21 119. The evidence amassed during and prior to the patent litigations showed  
22 that the patents purportedly covering Lidoderm would not withstand scrutiny.  
23 Moreover, the millions of dollars that Endo paid to Watson as part of the unlawful  
24 Agreement "provide a workable surrogate for [the] patent[s'] weakness[es]." *FTC v.*  
25 *Actavis, Inc.*, 570 U.S. \_\_\_, 133 S. Ct. 2223, 2236-37 (2013). "An unexplained  
26  
27

reverse payment,” like the payment at issue here, “itself would normally suggest that the patentee has serious doubts about the patent’s survival.” *Id.* at 2236.

### C. Anticompetitive Purpose and Effect of Defendants’ Conduct

120. The unlawful Reverse Payment Agreement enabled Defendants to: (a) delay the entry of less expensive generic versions of Lidoderm products in the United States for up to 13 months; (b) delay the introduction of an authorized generic lidocaine patch 5% for 7½ months, which otherwise would have appeared on the market coincident with initial generic competition; (c) fix, raise, maintain or stabilize the price of lidocaine patch 5% products; (d) maintain a monopoly in the U.S. market for lidocaine patch 5% products; (e) allocate 100% of the United States market for lidocaine patch 5% to Endo/Teikoku for up to 13 months; and (f) allocate 100% of United States sales of generic lidocaine patch 5% to Watson for 7½ months.

121. Moreover, Endo/Teikoku’s no-authorized-generic promise effectuated a naked market allocation and/or output restriction. Specifically, Endo/Teikoku abstained from competing with its horizontal competitor, Watson, by promising not to launch an authorized generic version of Lidoderm. Watson had no intellectual property covering authorized generic versions of Lidoderm, and so Endo/Teikoku’s promise to Watson to withhold an authorized generic is entitled to treatment as *per se* illegal and need not be treated under the rule of reason.

122. But for the unlawful Agreement: (a) Watson would have begun selling its generic version of Lidoderm when it received FDA approval on August 23, 2012 or shortly thereafter, either “at risk” or pursuant to an agreement with Endo/Teikoku that did not include a reverse payment; and (b) Endo/Teikoku would have launched an authorized generic lidocaine patch 5% simultaneously with Watson’s earlier entry.

123. Watson would have launched its generic product notwithstanding any patents that Endo/Teikoku may have claimed covered Lidoderm, prior to resolution of

1 the '529 Litigation, and prior to resolution of the Rolf Patent Litigation. None of the  
2 patents other than the '529 patent was even listed in the Orange Book when Watson  
3 filed its ANDA. Thus, Watson was not required to certify to any other patents under  
4 Hatch-Waxman, and any litigation filed over those other patents would not, and could  
5 not, result in a 30 month Hatch-Waxman stay of FDA approval of Watson's ANDA.  
6 Given the obvious defects in the '529 patent and Rolf patents, Watson would have  
7 launched upon final FDA approval even in the absence of a court ruling on those  
8 patents. Once Watson obtained FDA approval of its ANDA, it was free to launch, and  
9 but for the unlawful reverse payments, Watson would have launched its generic  
10 Lidoderm immediately, and Endo/Teikoku would have launched an authorized generic  
11 simultaneously.

12 124. Watson told Wall Street analysts in late 2011 and early 2012 that it was  
13 pursuing its ANDA, that it was closely monitoring the progress of the ANDA and  
14 expected approval in 2012, that its efforts to increase capacity were well underway,  
15 and it expected to be "ready to go at the earliest possible time to launch the product."

16 125. Alternatively, but for the unlawful reverse payments Endo/Teikoku and  
17 Watson would have entered into a procompetitive settlement agreement under which  
18 Endo/Teikoku would not have paid Watson for delay, Watson would have entered the  
19 market much earlier than September of 2013, and Endo/Teikoku would have  
20 simultaneously launched an authorized generic lidocaine patch 5%.

21 126. Defendants' unlawful actions have delayed the sale of generic Lidoderm  
22 in the United States, delayed the sale of an authorized generic Lidoderm in the United  
23 States, and unlawfully enabled Endo/Teikoku, and then Watson, to sell lidocaine patch  
24 5% at artificially inflated, supracompetitive prices. But for Defendants' illegal  
25 conduct, generic competition to Lidoderm would have begun prior to September 15,  
26  
27

2013, and would have included both Watson's generic Lidoderm product as well as Endo/Teikoku's authorized generic Lidoderm.

### **VIII. INTERSTATE COMMERCE**

127. At all material times, Endo/Teikoku manufactured, promoted, distributed, and sold substantial amounts of Lidoderm (and Watson manufactured, promoted, distributed, and sold substantial amounts of generic Lidoderm) in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States, including its territories, possessions and the Commonwealth of Puerto Rico.

128. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Lidoderm and generic Lidoderm.

129. In furtherance of their efforts to monopolize and restrain competition in the market for lidocaine patch 5%, Defendants employed the United States mail and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

### **IX. MONOPOLY POWER AND MARKET DEFINITION**

130. At all relevant times, Endo/Teikoku had market and/or monopoly power over lidocaine patch 5% because they had the power to maintain lidocaine patch 5% prices at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Lidoderm, with the exception of AB-rated generic versions of Lidoderm.

1           131. A small but significant, non-transitory price increase to Lidoderm by  
2 Endo/Teikoku would not have caused a significant loss of sales to drug products other  
3 than AB-rated generic versions of Lidoderm.

4           132. Lidoderm does not exhibit significant, positive cross elasticity of demand  
5 with respect to price with any product other than AB-rated generic versions of  
6 Lidoderm.

7           133. Because of, among other reasons, its approved indication, Lidoderm is  
8 differentiated from all products other than AB-rated generic versions of Lidoderm.

9           134. Endo/Teikoku needed to control only Lidoderm and its AB-rated generic  
10 equivalents, and no other products, in order to maintain the price of Lidoderm  
11 profitably at supracompetitive prices. Only the market entry of a competing, AB-rated  
12 generic version of Lidoderm would render Endo/Teikoku unable to profitably  
13 maintain its supracompetitive prices for Lidoderm without losing substantial sales.

14           135. Endo/Teikoku sold Lidoderm at prices well in excess of marginal costs,  
15 and in excess of the competitive price, and enjoyed high profit margins.

16           136. Endo/Teikoku have had, and exercised, the power to exclude and restrict  
17 competition to Lidoderm and its AB-rated generics.

18           137. Endo/Teikoku's reverse payments to Watson demonstrate that  
19 Endo/Teikoku enjoyed market and/or monopoly power with respect to lidocaine patch  
20 5%.

21           138. Endo/Teikoku, at all relevant times, enjoyed high barriers to entry with  
22 respect to competition to the above-defined relevant product market due to patent and  
23 other regulatory protections and high costs of entry and expansion.

24           139. To the extent that Plaintiffs may be legally required to prove market  
25 and/or monopoly power circumstantially by first defining a relevant product market,  
26 Plaintiffs allege that the relevant market is lidocaine patch 5% (*i.e.*, Lidoderm and its  
27

1 AB-rated generic equivalents). During the period relevant to this case, Endo/Teikoku  
2 were able to profitably maintain the price of lidocaine patch 5% well above  
3 competitive levels.

4 140. The relevant geographic market is the United States, including its  
5 territories, possessions and the Commonwealth of Puerto Rico.

6 141. At all relevant times, Endo/Teikoku's market share in the relevant market  
7 was 100%, implying a substantial amount of market power.

#### 8 **X. EFFECTS ON COMPETITION AND DAMAGES**

9 142. Watson's ANDA was approved August 23, 2012. Were it not for the  
10 unlawful reverse payments and Reverse Payment Agreement alleged herein, Watson  
11 would have entered the market on or shortly after that date. One or more generic  
12 Lidoderm products would have entered the market well before the date provided in  
13 Defendants' unlawful Reverse Payment Agreement, September 15, 2013.

14 143. But for the unlawful Reverse Payment Agreement, an authorized generic  
15 version of Lidoderm would have been available on the market simultaneously with the  
16 launch of Watson's generic.

17 144. Defendants' unlawful reverse payments and Reverse Payment Agreement  
18 delayed generic Lidoderm competition and unlawfully enabled Endo/Teikoku to sell  
19 Lidoderm without generic competition. But for Defendants' illegal conduct, one or  
20 more generic competitors would have begun marketing AB-rated generic versions of  
21 Lidoderm on August 23, 2012 or shortly thereafter, and in any event, earlier than  
22 September 15, 2013.

23 145. Watson had extensive experience in the pharmaceutical industry,  
24 including in obtaining approval for ANDAs, marketing generic pharmaceutical  
25 products, and manufacturing commercial launch quantities adequate to meet market  
26 demand.

1           146. Defendants' unlawful Reverse Payment Agreement, which delayed  
2 introduction of generic versions of Lidoderm in the United States, has caused  
3 Plaintiffs and the Class to pay more than they would have paid for lidocaine patch 5%.

4           147. Typically, generic versions of brand drugs are initially priced  
5 significantly below the corresponding brand drug to which they are AB-rated. As a  
6 result, upon generic entry, some or all of the direct purchases of brand drugs are  
7 rapidly substituted with generic versions of the drug. As more generic manufacturers  
8 enter the market, prices for generic versions of a drug predictably plunge even further  
9 because of competition among the generic manufacturers, and, correspondingly, the  
10 brand drug continues to lose even more sales to the generics.

11           148. This price competition enables all direct purchasers of the drugs to: (a)  
12 purchase generic versions of a drug at a substantially lower price, and/or (b) purchase  
13 the brand drug at a reduced price. Consequently, brand drug manufacturers have a  
14 keen financial interest in delaying the onset of generic competition, and purchasers  
15 experience substantial cost inflation from that delay.

16           149. But for Defendants' unlawful Agreement, direct purchasers, such as  
17 Plaintiffs and members of the Class, would have paid less for lidocaine patch 5% by  
18 (a) substituting purchases of less-expensive AB-rated generic Lidoderm for their  
19 purchases of more-expensive brand Lidoderm, (b) receiving discounts on their  
20 remaining brand Lidoderm purchases, and/or (c) purchasing generic Lidoderm at  
21 lower prices sooner.

22           150. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of  
23 the benefits of competition that the antitrust laws were designed to protect.

24           151. During the relevant period, Plaintiffs and other members of the Class  
25 purchased substantial amounts of Lidoderm directly from Endo/Teikoku and  
26 purchased substantial amounts of generic Lidoderm directly from Watson. As a result  
27

of Defendants' illegal conduct as alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their lidocaine patch 5% requirements. Plaintiffs and the other Class members paid prices for lidocaine patch 5% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic Lidoderm instead of more expensive brand Lidoderm; and (2) Class members paid artificially inflated prices for lidocaine patch 5%.

152. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

## **XI. CLAIMS FOR RELIEF**

### **CLAIM I: VIOLATION OF 15 U.S.C. § 1 (AGREEMENT UNREASONABLY RESTRAINING TRADE)**

153. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

154. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

155. In or about May 2012 and at times prior to the formal execution thereof Defendants entered into the Reverse Payment Agreement, an illegal contract, combination and conspiracy in restraint of trade under which Endo/Teikoku agreed to make large reverse payments to Watson in exchange for Watson's agreement to delay bringing its generic version of Lidoderm to the market for up to 13 months, the purpose and effect of which were to: (a) allocate 100% of the market for lidocaine patch 5% in the United States, including its territories, possessions and the

Commonwealth of Puerto Rico, to Endo/Teikoku; (b) delay the availability of generic versions of Lidoderm in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, thereby protecting Lidoderm from any generic competition; (c) delay the entry of Endo/Teikoku's authorized generic until 7½ months after Watson's entry with a generic Lidoderm product, and allocate 100% of sales for generic lidocaine patch 5% in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Watson prior to that time; and (d) fix, at supracompetitive levels, the price at which direct purchasers would pay for lidocaine patch 5%.

156. The Agreement harmed Plaintiffs and the Class as set forth above.

157. Defendants are liable for the Agreement under a rule of reason standard.

158. There is and was no legitimate, non-pretextual, procompetitive justification for the payment from Endo/Teikoku to Watson that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

159. As a direct and proximate result of Defendants' agreement in restraint of trade, as alleged herein, Plaintiffs and the Class were harmed and suffered overcharge damages as aforesaid.

**CLAIM II: VIOLATION OF 15 U.S.C. § 1  
(AGREEMENT *PER SE* UNREASONABLY RESTRAINING TRADE)**

160. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

161. Beginning in or about September 2013 and continuing through April 2014, Endo/Teikoku and Watson engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, in which Endo/Teikoku refrained from selling its competing authorized generic version of Lidoderm for 7½ months, to cede all generic

1 Lidoderm sales to Watson. Endo/Teikoku and Watson did this pursuant to the no-  
2 authorized-generic promise contained in the Reverse Payment Agreement.

3 162. In and of itself, Endo/Teikoku's promise not to launch an authorized  
4 generic version of Lidoderm constituted a naked agreement with Watson not to  
5 compete, a naked market allocation agreement with Watson (which allocated 100% of  
6 sales of generic Lidoderm to Watson), and a concerted output restriction during the 7½  
7 month period after Watson entered the market with its generic Lidoderm.

8 163. The Agreement harmed Plaintiffs and the Class as set forth above.

9 164. Defendants are *per se* liable for the no-authorized-generic agreement.  
10 Watson had no patent purportedly covering authorized generic Lidoderm, and so the  
11 justification for application of the rule of reason is absent.

12 165. Alternatively, Defendants are liable for the no-authorized-generic  
13 agreement under a rule of reason standard.

14 166. Insofar as the rule of reason applies, there is and was no legitimate, non-  
15 pretextual, procompetitive justification for the no-authorized-generic agreement  
16 between Defendants that outweighs its harmful effect. Even if there were some  
17 conceivable such justification, the no-authorized-generic agreement was not necessary  
18 to achieve, nor the least restrictive means of achieving, such a purpose.

19 167. As a direct and proximate result of Defendants' agreement in restraint of  
20 trade, as alleged herein, Plaintiffs and the Class were harmed and suffered overcharge  
21 damages as aforesaid.

22 **CLAIM III: VIOLATION OF 15 U.S.C. § 2**  
23 **(CONSPIRACY TO MONOPOLIZE)**

24 168. Plaintiffs hereby incorporate each preceding and succeeding paragraph as  
25 though fully set forth herein.  
26  
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1           169. At all relevant times, Endo/Teikoku possessed substantial market power  
2 (*i.e.*, monopoly power) in the relevant market. Endo/Teikoku possessed the power to  
3 control prices in, prevent prices from falling in, and exclude competitors from, the  
4 relevant market.

5           170. Through the Reverse Payment Agreement, Endo/Teikoku and Watson  
6 conspired to maintain Endo/Teikoku's monopoly power in the relevant market in order  
7 to block and delay market entry of generic Lidoderm.

8           171. The Reverse Payment Agreement (a) allocated 100% of the market for  
9 lidocaine patch 5% in the United States, including its territories, possessions and the  
10 Commonwealth of Puerto Rico, to Endo/Teikoku; (b) delayed the availability of  
11 generic versions of Lidoderm in the United States, including its territories,  
12 possessions and the Commonwealth of Puerto Rico, thereby protecting Lidoderm from  
13 any generic competition; (c) delayed the entry of Endo/Teikoku's authorized generic  
14 until 7½ months after Watson's entry with a generic Lidoderm product, and allocate  
15 100% of sales for generic lidocaine patch 5% in the United States, including its  
16 territories, possessions and the Commonwealth of Puerto Rico, to Watson prior to that  
17 time; and (d) fixed, at supracompetitive levels, the price at which direct purchasers  
18 would pay for lidocaine patch 5%.

19           172. The goal, purpose and/or effect of the Agreement was to maintain and  
20 extend Endo/Teikoku's monopoly power in the United States market, including its  
21 territories, possessions and the Commonwealth of Puerto Rico, in the market for  
22 lidocaine patch 5%, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The  
23 Agreement was intended to and did prevent and/or delay generic competition to  
24 Lidoderm and enabled Endo/Teikoku to continue charging supracompetitive prices for  
25 Lidoderm without a substantial loss of sales.  
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173. Defendants knowingly and intentionally conspired to maintain and enhance Endo/Teikoku's monopoly power in the relevant market.

174. Defendants specifically intended that their Agreement would maintain Endo/Teikoku's monopoly power in the relevant market, and injured Plaintiffs and the Class thereby.

175. Defendants each committed at least one overt act in furtherance of the conspiracy.

176. As a direct and proximate result of Defendants' concerted monopolistic conduct, as alleged herein, Plaintiffs and the Class were harmed as aforesaid.

**COUNT IV: VIOLATION OF 15 U.S.C. § 2  
(MONOPOLIZATION)**

177. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

178. This claim is pled as to Endo/Teikoku only.

179. At all relevant times, Endo/Teikoku possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Endo/Teikoku possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

180. Through the anticompetitive conduct, as alleged extensively above, Endo/Teikoku willfully maintained their monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

181. It was Endo/Teikoku's conscious object to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

182. Endo/Teikoku's anticompetitive conduct harmed competition as alleged herein.

1           183. As a direct and proximate result of Endo/Teikoku's illegal and  
2 monopolistic conduct, as alleged herein, Plaintiffs and the Class were harmed as  
3 alleged herein.

4                           **COUNT V: VIOLATION OF 15 U.S.C. § 2**  
5                           **(ATTEMPTED MONOPOLIZATION)**

6           184. Plaintiffs hereby incorporate each preceding and succeeding paragraph as  
7 though fully set forth herein.

8           185. This claim is pled as to Endo/Teikoku only.

9           186. Through the Reverse Payment Agreement, Endo/Teikoku specifically  
10 intended to maintain monopoly power in the relevant market. It was Endo/Teikoku's  
11 conscious objective to control prices and/or to exclude competition in the relevant  
12 market.

13           187. The natural and probable consequence of Endo/Teikoku's anticompetitive  
14 conduct, which was intended by them, and plainly foreseeable to them, was to control  
15 prices and exclude competition in the relevant market, to the extent it did not succeed.

16           188. There was a substantial and real chance, a reasonable likelihood, and/or a  
17 dangerous probability that Endo/Teikoku would succeed in and achieve their goal of  
18 maintaining monopoly power in the relevant market.

19           189. As a direct and proximate result of Endo/Teikoku's illegal and  
20 monopolistic conduct, Plaintiffs and the Class were harmed as alleged herein.

21                           **XII. DEMAND FOR JUDGMENT**

22           WHEREFORE, Plaintiffs, on behalf of themselves and the Class, respectfully  
23 request that the Court:

24           A. Determine that this action may be maintained as a class action pursuant to  
25 Fed. R. Civ. P. 23(a) and (b)(3), direct that reasonable notice of this action, as  
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1 provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiffs  
2 as the representatives of the Class;

3 B. Enter joint and several judgments against Defendants and in favor of  
4 Plaintiffs and the Class;

5 C. Award the Class damages (*i.e.*, three times overcharges) in an amount to  
6 be determined at trial; and

7 D. Award Plaintiffs and the Class their costs of suit, including reasonable  
8 attorneys' fees as provided by law.

9 **XIII. JURY DEMAND**

10 Pursuant to Fed. Civ. P. 38, Plaintiffs, on behalf of themselves and the proposed  
11 Class, demand a trial by jury on all issues so triable.  
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Respectfully submitted,

3 /s/ Peter R. Kohn

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